UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------------------------------|----------------------|---------------------|------------------|
| 10/748,477 | 12/30/2003 | Kay L. Grasso | CRNI.107715 | 7079 |
| | 7590 11/18/200 DY & BACON L.L.P. | EXAMINER | | |
| Intellectual Property Department | | | SQUIRES, ELIZA A | |
| 2555 GRAND BOULEVARD KANSAS CITY, MO 64108-2613 | | | ART UNIT | PAPER NUMBER |
| | | | 3626 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 11/18/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | Application No. | Applicant(s) | | | |
|--|---|------------------------------------|-----------------------|--|--|--|
| Office Action Summary | | 10/748,477 | GRASSO ET AL. | | | |
| | | Examiner | Art Unit | | | |
| | | Eliza Squires | 3626 | | | |
| Period fo | The MAILING DATE of this communication app r Reply | ears on the cover sheet with the c | orrespondence address | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1) | Responsive to communication(s) filed on <u>03 Au</u> | iaust 2009 | | | | |
| · · · · · · · · · · · · · · · · · · · | This action is FINAL . 2b) This action is non-final. | | | | | |
| ′= | ·— | | | | | |
| • | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| | closed in accordance with the practice under 2 | A parte Quayle, 1999 O.D. 11, 40 | 0.0.210. | | | |
| Dispositi | on of Claims | | | | | |
| 4)🛛 | I)⊠ Claim(s) <u>1-7,26-29,46 and 51-57</u> is/are pending in the application. | | | | | |
| 4 | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5) | 5) Claim(s) is/are allowed. | | | | | |
| 6)🖂 | 6)⊠ Claim(s) <u>1-7, 26-29, 46, and 51-57</u> is/are rejected. | | | | | |
| 7) | Claim(s) is/are objected to. | | | | | |
| 8) | Claim(s) are subject to restriction and/or | r election requirement. | | | | |
| Application | on Papers | | | | | |
| 9) ☐ The specification is objected to by the Examiner. | | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| | • | priority under 35 LLS C & 110(a) | (d) or (f) | | | |
| _ | 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | |
| عار ا | a) All b) Some * c) None of: | | | | | |
| | 1. Certified copies of the priority documents have been received. | | | | | |
| | 2. Certified copies of the priority documents have been received in Application No | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date Notice of Informal Patent Application | | | | | | |
| Paper No(s)/Mail Date 6) Other: | | | | | | |

Application/Control Number: 10/748,477 Page 2

Art Unit: 3626

DETAILED ACTION

The Amendment dated 8/3/2009 has been entered. Claims 1-4, 26, and 46 has been amended. Claim 41 has been canceled and claims 51-57 have been added. Claims 1-7, 26-29, 46, and 51-57 are pending in the application.

Response to Arguments

- 1. Applicant's arguments with respect to claim 1-7, 26-29, 46, and 51-57 have been considered but are moot in view of the new ground(s) of rejection.
- 2. The rejections under 35 USC 101 and 112 previously presented in the Office Action dated 4/2/2009 has been withdrawn in light of Applicant's amendment.

Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 1-7, 26-29, 46, and 51-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,985,870 to *Martucci et al.*.
- 5. **As to claims 1 and 26,** *Martucci* discloses a computer-implemented_method in a computer

system for preventing one or more medications from being administered to a person too early, the method comprising:

receiving from a clinician, utilizing a first computer process, an identification of an medication to be administered to a person, wherein the identification of the medication is input

by the clinician during a clinical visit with the person (*Martucci* figure 7 and column 4 lines 18-50);

Page 3

in response to receiving the identification of the medication to be administered during the clinical visit, determining, utilizing a second computer process, whether it is too soon to administer the medication (*Martucci* figures 15 (j) and (k) and column 11 lines 38-45); and

based on a determination that it is too soon to administer the medication, displaying a warning that the medication is being administered too soon (*Martucci* figures 15 (j) and (k) and column 11 lines 38-45),

wherein the first and second computer processes are executed utilizing one or more computing devices (*Marucci* see "handheld computing device" in at least the abstract).

Martucci does not explicitly teach that the medication is an immunization, however, the fact that the fluid delivered to a patient is an immunization does not effect any of the steps in the method, therefore, the type of fluid, an immunization is non-functional. Additionally, it would be simple substitution to substitute an immunization for the medication of *Martucci*.

6. **As to claims 2 and 27,** see the discussion of claim 1, additionally, *Martucci* discloses the method further comprising:

upon determining that it is too soon to administer the medicine, determining it is still safe to administer the medicine (*Martucci* figures 15 (j) and (k) and column 11 lines 38-45 wherein a practitioner can choose to continue or to cancel the medication delivery when alerted).

7. **As to claims 3 and 28,** see the discussion of claims 1 and 2, additionally, *Martucci* discloses the method further comprising:

Application/Control Number: 10/748,477 Page 4

Art Unit: 3626

based on a determination that it is still safe to administer the medicine, wherein if it is safe to administer the medicine, outputting information that it is safe to administer the medicine (*Martucci* figures 13 (a) and (b)).

8. **As to claims 4 and 29,** see the discussion of claims 1 and 2, additionally, *Martucci* discloses the method further comprising further comprising:

upon determining that it is too soon to administer the medicine, determining that it is not safe to administer the medicine; and

based on a determination that it is not safe to administer the medicine, wherein if it is not safe to administer the medicine, outputting information that it is not safe to administer the medicine (*Martucci* Figure 39).

9. **As to claim 5,** see the discussion of claim 1 additionally *Martucci* discloses the method further comprising:

obtaining information regarding the safe timing of medications from a database (*Martucci* figures 15 (j) and (k) and column 11 lines 38-45).

10. **As to claim 6,** see the discussion of claims 1 and 5 additionally *Martucci* discloses the method further comprising:

obtaining information from an electronic medical record of the person stored within a comprehensive healthcare system (*Martucci* column 8 lines 40-57).

11. **As to claim 7,** see the discussion of claims 1 and 5-6 additionally *Martucci* discloses the method further comprising:

Application/Control Number: 10/748,477

Art Unit: 3626

utilizing the information from the electronic medical record of the person and the information regarding safe timing of medications to determine whether an immunization is being administered too soon (*Martucci* figures 15 (j) and (k) and column 11 lines 38-45).

Page 5

12. **As to claim 46,** *Martucci* discloses a computer-storage medium having computer-executable instructions for performing a method for preventing one or more immunizations from being administered to a person too early, the method comprising:

receiving from a clinician an identification of a medication to be administered to a person, wherein the identification of the immunization is input by the clinician during a clinical visit with the person (*Martucci* figure 7 and column 4 lines 18-50);

in response to receiving the identification of the medication to be administered to the person during the clinical visit, determining whether it is too soon to administer the medication during the clinical visit; and

based on a determination that it is too soon to administer the medication, displaying a warning that the medication is being administered too soon, wherein the warning is a first popup warning window (*Martucci* figures 15 (j) and (k) and column 11 lines 38-45);

based on a determination this it is not too soon to administer the medication, determining whether the medication will cause an adverse reaction to the person (*Martucci* Figure 39).

upon determining that the medication will cause an adverse reaction, displaying a warning that the medication will cause an adverse reaction via a second pop-up warning window (*Martucci* Figure 39).

Application/Control Number: 10/748,477 Page 6

Art Unit: 3626

upon determining that the medication will not cause an adverse reaction, displaying a message that the medication may be administered during the clinical visit (*Martucci* figures 13 (a) and (b)).

Martucci does not explicitly teach that the medication is an immunization, however, the fact that the fluid delivered to a patient is an immunization does not effect any of the steps in the method, therefore, the type of fluid, an immunization is non-functional. Additionally, it would be simple substitution to substitute an immunization for the medication of *Martucci*.

13. **As to claim 51,** see the discussion of claim 46, additionally, *Martucci* discloses the computer storage medium further comprising:

obtaining healthcare information for the person from the person's electronic medical record (*Martucci* column 8 lines 40-57).

- 14. **As to claim 52,** see the discussion of claim 46, additionally, *Martucci* discloses the computer-readable medium further comprising: obtaining information regarding adverse reactions and immunizations (*Martuchi* column 11 lines 58-67).
- 15. **As to claim 53,** see the discussion of claim 46 and 52, additionally, *Martucci* discloses the computer-readable medium further comprising:

comparing the information regarding adverse reactions to the information for the person obtained from the person's electronic medical record (*Martucci* column 8 lines 58-67).

16. **As to claim 54,** see the discussion of claims 46 and 52-53, additionally, *Martucci* discloses the computer-readable medium wherein the information obtained from the person's electronic medical record includes medications being taken (*Martucci* column 8 lines 58-67).

Application/Control Number: 10/748,477

Art Unit: 3626

17. **As to claim 55,** see the discussion of claims 46 and 52-53, additionally, *Martucci* discloses the computer-readable medium wherein the information obtained from the person's electronic medical record includes allergy information (*Martucci* column 8 lines 58-67).

Page 7

- 18. **As to claim 56,** see the discussion of claim 46 and 52-53, additionally, *Martucci* discloses the computer-readable medium wherein the information obtained from the person's electronic medical record includes a medical condition that can cause adverse reactions to the medication (*Martucci* column 8 lines 58-67 where in a medical condition is an allergy).
- 19. **As to claim 57,** see the discussion of claim 46 and 52-53, additionally, *Martucci* discloses The computer-readable medium wherein the information obtained from the person's electronic medical record includes a genetic condition that predisposes the person to adverse reactions to the immunizations (*Marrucci* column 8 lines 58-67 where in a medical condition is an allergy and an allergy is a "complex genetic disorder" (The Genetics of Athsma Am. J. Respir. Crit. Care Med., Volume 161, Number 3, March 2000, S202-S206).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliza Squires whose telephone number is (571)270-7052. The examiner can normally be reached on Monday through Friday 8 am - 4 pm Eastern Standard Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. S./ Examiner, Art Unit 3626

/C. Luke Gilligan/ Supervisory Patent Examiner, Art Unit 3626